

## REMARKS/ARGUMENTS

### **1. Status of Claims**

Claims 13-18 and 23-25 are currently pending.

### **2. Support for Amendments**

Support for the amended claims can be found in the specification as originally filed. Specifically, as noted by the Patent Office, support for “perimeter squared area” can be found on page 12, line 4 and support for “height width ratio” can be found on page 12, line 6. The claim amendments do not constitute new matter.

### **3. Claim rejections under 35 USC 112 first paragraph**

The Patent Office rejected claims 13-18 and 23-25 under 35 USC 112 first paragraph for failing to meet the written description requirement, based on the assertion that the claims represent new matter. Applicants traverse this rejection.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Newly added claim limitations must be supported in the specification through express, **implicit, or inherent disclosure**. The subject matter of the claim **need not be described literally** (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. Furthermore, what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. ***If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.*** (MPEP 2163)

Specifically, the patent office has asserted that the following terms do not have written support in the application as filed:

**(a) Subcellular:** The patent office asserted that “written support is provided for the image analysis of two particular subcellular components, the nucleus and cytoplasm, but not for ‘subcellular’ image data in general, which is broader in scope.” As noted above, the written description requirement is met if one of skill in the art **would have understood the**

***inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification.***

The Applicants point to page 12 lines 30-31 as support for introduction of “subcellular” into the claims. This passage states the following:

“Quantification of the difference between these two sub-cellular compartments provides a measure of cytoplasm-nuclear translocation.”

Furthermore, as admitted by the patent office, the specification provides support for two distinct examples of collecting image data for subcellular components, the nucleus and the cytoplasm. While this is true, the specification provides additional support for other sub-cellular compartments. For example, see page 12 (lines 1-31), 12 (lines 30-31), and page 19 (lines 1-17). On page 19, lines 3-15, the specification states:

***“Those skilled in the art will recognize a wide variety of distinct screens that can be developed. There is a large and growing list of known biochemical and molecular processes in cells that involve translocations or reorganizations of specific components within cells.***

The signaling pathway from the cell surface to target sites within the cell involves the translocation of *plasma membrane-associated proteins to the cytoplasm*. For example, it is known that one of the src family of protein tyrosine kinases, pp60c-src, translocates from the plasma membrane to the cytoplasm upon stimulation of fibroblasts with platelet-derived growth factor (PDGF). In contrast, some cytoplasmic components translocate from the cytoplasm to the plasma membrane upon stimulation of cells. For example, it is known that the GTP-binding proteins of the Rho family are maintained as cytoplasmic complexes with RhoGDI in resting cells, but are released and translocate to plasma membrane during cell activation. In addition, *specific organelles, such as components of the cytoskeleton, nuclear envelope, chromatin, golgi apparatus, mitochondria, and endosomes are reorganized in response to specific stimuli.*”

Those of skill in the art are well aware that the nucleus, cytoplasm, plasma membrane, cytoskeletal components, nuclear envelope, chromatin, golgi apparatus, mitochondria, and endosomes are all sub-cellular components. Further, as explicitly stated in this section, those of skill in the art will recognize that, based on the specification, a wide variety of distinct screens can be developed, based on the methods disclosed in the application combined with the large and growing list of known biochemical and molecular processes in cells that involve translocations or reorganizations of specific components

within cells. The Patent Office asserts in the instant office action that “developing screens is not the same thing as ‘collecting subcellular image data from the cell in the well’ or ‘storing the subcellular image in the computer system database.’” It would further be clear to those with skill in art that the purpose of “developing screens” is to collect and eventually store image data as detailed on page 13, line 25 through page 14, line 15. Thus, based on the teachings involving sub-cellular translocation between nucleus and cytoplasm, and the explicit teachings in the section recited above that these methods can be extended to other types of translocations and reorganizations involving components well known by those in the art to be sub-cellular, it is clear that those of skill in the art would have understood the inventors to be in possession of the claimed invention at the time of filing.

The Patent Office has still not provided any explanation or evidence why one of skill in the art would not have understood that the inventors were in possession of the claimed invention. As stated in the previous office action response, the patent office merely asserts that ‘subcellular’ “is broader in scope than nucleus and cytoplasm. However, this is not the proper test. As stated in MPEP 2163 the examiner has the initial burden of presenting evidence or reasoning to explain ***why persons skilled the art would not recognize in the original disclosure a description of the invention defined by the claims***, the initial burden is not set forth, as the Patent Office maintains in the instant office action “by stating what has written support and what doesn’t.” The initial burden, as stated in the MPEP, has still not been met or addressed in any substantive form, and, based on all of the above, it is clear that those of skill in the art would have understood the inventors to be in possession of the claimed invention at the time of filing.

Based on all of the above, the Applicants respectfully request reconsideration and withdrawal of the rejection.

**(b) Perimeter:** The patent office asserted that the specification provides support for “perimeter squared area” but not “perimeter.” The Applicants traverse this assertion but the claims have been amended to obviate the rejection.

**(c) Height:** The patent office asserted that the specification provides support for “height width ratio” but not “height.” The Applicants traverse this assertion but the claims have been amended to obviate the rejection.

**(d) Ratio of fluorescent intensities:** The patent office asserted that the specification provides support for “ratio of the average fluorescent intensity of the cytoplasmic mask to the average fluorescent intensity within the cell nucleus for colors 2-4” but not for “ratio of fluorescent intensities.” The Applicants traverse this assertion but the claims have been amended to obviate the rejection.

**(e) Difference in fluorescent intensities:** The patent office asserted that the specification provides support for “the difference of the average fluorescent intensity of the cytoplasmic mask and the average fluorescent intensity within the cell nucleus for colors 2-4” but not for “differences in fluorescent intensities.” The Applicants traverse this assertion but the claims have been amended to obviate the rejection.

#### **4. Claim rejections based on 35 USC §102(e)**

The Patent Office rejected claims 13-18 and 23-25 under 35 USC 102(e)(2) over Nova et al. (US Pat. No. 5,961,923). The Applicants traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. ***“To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’”*** (MPEP Section 2112, IV)

Presently pending claim 13 recites as follows:

A method for acquisition, storage, and retrieval of cell screening data on a computer system, comprising the steps of :

- a) providing a plate containing wells, wherein the wells comprise cells;
  - b) storing input parameters used for screening of the plate in a computer system database;
  - c) repeating steps (i)-(ix) for a desired number of wells:
    - i) selecting an individual well on the plate,
    - ii) collecting **subcellular image data** from the cells in the well,
    - iii) storing the **subcellular image data** in the computer system database,
    - iv) collecting **feature data** from the **subcellular image data**,
    - v) storing the feature data in the computer system database,
    - vi) calculating well summary data using the **subcellular image data** and the feature data collected from the well;
    - vii) storing the well summary data in the computer system database;
    - viii) calculating plate summary data using the well summary data from the computer system database; and
    - ix) storing the plate summary data in the computer system database;
- wherein the subcellular image data, the feature data, the well summary data, and the plate summary data can be retrieved from the computer system database.

Nova does not teach or suggest collecting **subcellular image data from individual cells** in the wells, nor, as a result, any further steps involving image data, as recited in the presently pending claims.

The Patent office asserts that “sub-cellular image data” is defined as “anything involving subcellular and image data (i.e. data from labeled proteins detected using a photodetector...)” and that Nova has taught collecting, storing, and retrieving subcellular image data according to this definition of subcellular. However, the Patent Office has provided no basis for this definition except for its own assertion and has failed to note the entirety of the instant claims, which state “collecting **subcellular image data from the cells...**” It would have been clear to one with skill in the art that the instant claims recite collecting image data from subcellular components within the cell and that Nova does not teach or suggest collecting subcellular image data from within cells. Nova teaches the use of labeled individual molecules, such as “antigens, antibodies, ligands, proteins and nucleic

acids” (column 7, lines 7-8), which are not located in a cell, and thus are not subcellular, nor are images of such molecules “subcellular images.”

The patent office cites column 51, line 61 to column 52, line 9 and lines 27-60 to support the assertion that Nova teaches image acquisition to monitor edges and peak signals, as well as determining the average intensity of each cell. However, the recited section (column 51 line 61 to column 52 line 9) teaches generating a “snap-shot” of the optical memory device. This does not expressly refer to collecting **subcellular image data from cells** in wells, nor does the section inherently anticipate collecting **subcellular image data from cells** in wells (ie: it is not *necessarily present*). Furthermore, column 52 lines 27-60 (and corresponding Figure 31) involve determining edges and peaks for the **symbol** (see column 52 lines 45, 48, and 57). As noted in column 22 line 65-67, symbology refers to the code, such as a bar code, that is engraved or imprinted on the optical memory device. Clearly, this does not expressly refer to collecting **subcellular image data from cells** in wells, nor does the section inherently anticipate collecting image data from cells in wells (ie: it is not *necessarily present*).

Contrary to the Patent Office’s assertion, the Applicants have in **no** way argued that Nova teaches the instant claim limitations but for a different purpose; but actually have clearly argued that Nova **does not** teach or suggest the instant claim limitations, regardless of purpose. Nova does not teach or suggest, for example, any of the following limitations of claim 13:

- collecting **subcellular image data from the cells** in the well,
- storing the **subcellular image data** in the computer system database,
- collecting **feature data** from the **subcellular image data**,
- storing the feature data (which is from the **subcellular image data**) in the computer system database,
- calculating well summary data **using the subcellular image data and the feature data** collected from the well;
- storing the well summary data (calculated from the **subcellular image data**) in the computer system database;
- calculating plate summary data using the well summary data (which is calculated from the **subcellular image data**) from the computer system database;
- storing the plate summary data (calculated from the well summary data which is calculated from the **subcellular image data**) in the computer system database; and

-wherein the **subcellular image data**, the feature data, the well summary data, and the plate summary data can be retrieved from the computer system database.


Thus, the Nova reference clearly is not a proper anticipatory reference for claim 13, nor for any of the claims dependent on claim 13, which recite further limitations. Based on all of the above, the applicants respectfully request reconsideration and withdrawal of this rejection.

If there are any questions or comments regarding this Response, the Patent Office is encouraged to contact the undersigned attorney as indicated below.

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